UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,390	01/23/2004	Arthur B. Raitano	511582008100	2022

25225 7590 06/12/2008

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
06/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,390	RAITANO ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,54,56-58,63,66,72,75,79 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,54,56-58,63,72,75,79 and 80* is/are rejected.

7)☐ Claim(s) *66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 9, 2008 has been entered.

Claims 49, 54, 56-58, 63, 66, 72, 75 and 79-80 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49, 57,63, 79 and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Mintz et al (2007/0083334, priority to September 13, 2002).

Claim 49 is drawn in part to a polypeptide comprising SEQ ID NO:5. Claim 63 is drawn in part to a polynucleotide encoding SEQ ID NO:5, or a polypeptide fully complementary thereto wherein T can also be U. Claim 57 is drawn in part to a pharmaceutical composition comprising SEQ ID NO:5 and a pharmaceutically acceptable carrier.

Mintz et al disclose the polypeptide and the polynucleotide encoding SEQ ID NO:747289 and 747290, as evidenced by the attached sequence alignment. One of skill in the art could readily envision the polynucleotide fully complementary to the polynucleotide encoding the polypeptide. Mintz et al disclose pharmaceutical composition comprising proteins of unknown function (paragraph [0413]). Claims 79 and 80 are included with this rejection because the polynucleotide are claimed as a product by process in that said polynucleotide is

used to encode a polypeptide as a portion of a viral vector. The polynucleotide encoding the polypeptides of SEQ ID NO:747289 and 747290 of Mintz et al meet the structural

```
      US-11-443-428A-747289
      ; Sequence 747289, Application US/11443428A
      ; GENERAL INFORMATION:
      ;  APPLICANT: Mintz, Liat
      ;  APPLICANT:  Xie, Hanqing
      ;  APPLICANT:  Dahari, Dvir
      ;  APPLICANT:  Levanon, Erez
      ;  APPLICANT:  Freilich, Shiri
      ;  APPLICANT:  Beck, Nili
      ;  APPLICANT:  Zhu, Wei-Yong
      ;  APPLICANT:  Wasserman, Alon
      ;  APPLICANT:  Hermesh, Chen
      ;  APPLICANT:  Azar, Idit
      ;  APPLICANT:  Bernstein, Jeanne
      ;  TITLE OF INVENTION: METHODS AND SYSTEMS USEFUL FOR ANNOTATING BIOMOLECULAR
SEQUENCES
      ;  FILE REFERENCE: 02/23929
      ;  CURRENT APPLICATION NUMBER: US/11/443,428A
      ;  CURRENT FILING DATE:  2006-05-31
      ;  NUMBER OF SEQ ID NOS: 1034312
      ;  SOFTWARE: PatentIn version 3.1
      ; SEQ ID NO 747289
      ;   LENGTH: 1072
      ;   TYPE: PRT
      ;   ORGANISM: Homo sapiens
      US-11-443-428A-747289

        Query Match             100.0%;  Score 5592;  DB 44;  Length 1072;
        Best Local Similarity   100.0%;  Pred. No. 0;
        Matches 1072;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

      Qy          1 MAPPTGVLSSLLLLVTIAGCARKQCSEGRTYSNAVISPNLETTRIMRVSHTFPVVDCTAA 60
                    ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
      Db          1 MAPPTGVLSSLLLLVTIAGCARKQCSEGRTYSNAVISPNLETTRIMRVSHTFPVVDCTAA 60

      Qy         61 CCDLSSCDLAWWFEGRCYLVSCPHKENCEPKKMGPIRSYLTFVLRPVQRPAQLLDYGDMM 120
```

```
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        61 CCDLSSCDLAWWFEGRCYLVSCPHKENCEPKKMGPIRSYLTFVLRPVQRPAQLLDYGDMM 120

Qy       121 LNRGSPSGIWGDSPEDIRKDLPFLGKDWGLEEMSEYADDYRELEKDLLQPSGKQEPRGSA 180
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       121 LNRGSPSGIWGDSPEDIRKDLPFLGKDWGLEEMSEYADDYRELEKDLLQPSGKQEPRGSA 180

Qy       181 EYTDWGLLPGSEGAFNSSVGDSPAVPAETQQDPELHYLNESASTPAPKLPERSVLLPLPT 240
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       181 EYTDWGLLPGSEGAFNSSVGDSPAVPAETQQDPELHYLNESASTPAPKLPERSVLLPLPT 240

Qy       241 TPSSGEVLEKEKASQLQEQSSNSSGKEVLMPSHSLPPASLELSSVTVEKSPVLTVTPGST 300
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       241 TPSSGEVLEKEKASQLQEQSSNSSGKEVLMPSHSLPPASLELSSVTVEKSPVLTVTPGST 300

Qy       301 EHSIPTPPTSAAPSESTPSELPISPTTAPRTVKELTVSAGDNLIITLPDNEVELKAFVAP 360
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       301 EHSIPTPPTSAAPSESTPSELPISPTTAPRTVKELTVSAGDNLIITLPDNEVELKAFVAP 360

Qy       361 APPVETTYNYEWNLISHPTDYQGEIKQGHKQTLNLSQLSVGLYVFKVTVSSENAFGEGFV 420
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       361 APPVETTYNYEWNLISHPTDYQGEIKQGHKQTLNLSQLSVGLYVFKVTVSSENAFGEGFV 420

Qy       421 NVTVKPARRVNLPPVAVVSPQLQELTLPLTSALIDGSQSTDDTEIVSYHWEEINGPFIEE 480
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       421 NVTVKPARRVNLPPVAVVSPQLQELTLPLTSALIDGSQSTDDTEIVSYHWEEINGPFIEE 480

Qy       481 KTSVDSPVLRLSNLDPGNYSFRLTVTDSDGATNSTTAALIVNNAVDYPPVANAGPNHTIT 540
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       481 KTSVDSPVLRLSNLDPGNYSFRLTVTDSDGATNSTTAALIVNNAVDYPPVANAGPNHTIT 540

Qy       541 LPQNSITLNGNQSSDDHQIVLYEWSLGPGSEGKHVVMQGVQTPYLHLSAMQEGDYTFQLK 600
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       541 LPQNSITLNGNQSSDDHQIVLYEWSLGPGSEGKHVVMQGVQTPYLHLSAMQEGDYTFQLK 600

Qy       601 VTDSSRQQSTAVVTVIVQPENNRPPVAVAGPDKELIFPVESATLDGSSSSDDHGIVFYHW 660
                 ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       601 VTDSSRQQSTAVVTVIVQPENNRPPVAVAGPDKELIFPVESATLDGSSSSDDHGIVFYHW 660

Qy       661 EHVRGPSAVEMENIDKAIATVTGLQVGTYHFRLTVKDQQGLSSTSTLTVAVKKENNSPPR 720
```

```
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        661 EHVRGPSAVEMENIDKAIATVTGLQVGTYHFRLTVKDQQGLSSTSTLTVAVKKENNSPPR 720

Qy        721 ARAGGRHVLVLPNNSITLDGSRSTDDQRIVSYLWIRDGQSPAAGDVIDGSDHSVALQLTN 780
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        721 ARAGGRHVLVLPNNSITLDGSRSTDDQRIVSYLWIRDGQSPAAGDVIDGSDHSVALQLTN 780

Qy        781 LVEGVYTFHLRVTDSQGASDTDTATVEVQPDPRKSGLVELTLQVGVGQLTEQRKDTLVRQ 840
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        781 LVEGVYTFHLRVTDSQGASDTDTATVEVQPDPRKSGLVELTLQVGVGQLTEQRKDTLVRQ 840

Qy        841 LAVLLNVLDSDIKVQKIRAHSDLSTVIVFYVQSRPPFKVLKAAEVARNLHMRLSKEKADF 900
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        841 LAVLLNVLDSDIKVQKIRAHSDLSTVIVFYVQSRPPFKVLKAAEVARNLHMRLSKEKADF 900

Qy        901 LLFKVLRVDTAGCLLKCSGHGHCDPLTKRCICSHLWMENLIQRYIWDGESNCEWSIFYVT 960
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        901 LLFKVLRVDTAGCLLKCSGHGHCDPLTKRCICSHLWMENLIQRYIWDGESNCEWSIFYVT 960

Qy        961 VLAFTLIVLTGGFTWLCICCCKRQKRTKIRKKTKYTILDNMDEQERMELRPKYGIKHRST 1020
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        961 VLAFTLIVLTGGFTWLCICCCKRQKRTKIRKKTKYTILDNMDEQERMELRPKYGIKHRST 1020

Qy       1021 EHNSSLMVSESEFDSDQDTIFSREKMERGNPKVSMNGSIRNGASFSYCSKDR 1072
                ||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1021 EHNSSLMVSESEFDSDQDTIFSREKMERGNPKVSMNGSIRNGASFSYCSKDR 1072
```

US-11-443-428A-747290
; Sequence 747290, Application US/11443428A
; GENERAL INFORMATION:
; APPLICANT: Mintz, Liat
; APPLICANT: Xie, Hanqing
; APPLICANT: Dahari, Dvir
; APPLICANT: Levanon, Erez
; APPLICANT: Freilich, Shiri
; APPLICANT: Beck, Nili
; APPLICANT: Zhu, Wei-Yong
; APPLICANT: Wasserman, Alon
; APPLICANT: Hermesh, Chen
; APPLICANT: Azar, Idit

; APPLICANT: Bernstein, Jeanne
; TITLE OF INVENTION: METHODS AND SYSTEMS USEFUL FOR ANNOTATING BIOMOLECULAR SEQUENCES
; FILE REFERENCE: 02/23929
; CURRENT APPLICATION NUMBER: US/11/443,428A
; CURRENT FILING DATE: 2006-05-31
; NUMBER OF SEQ ID NOS: 1034312
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 747290
; LENGTH: 1072
; TYPE: PRT
; ORGANISM: Homo sapiens
US-11-443-428A-747290

Query Match 100.0%; Score 5592; DB 44; Length 1072;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 1072; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy          1 MAPPTGVLSSLLLLVTIAGCARKQCSEGRTYSNAVISPNLETTRIMRVSHTFPVVDCTAA 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MAPPTGVLSSLLLLVTIAGCARKQCSEGRTYSNAVISPNLETTRIMRVSHTFPVVDCTAA 60

Qy         61 CCDLSSCDLAWWFEGRCYLVSCPHKENCEPKKMGPIRSYLTFVLRPVQRPAQLLDYGDMM 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 CCDLSSCDLAWWFEGRCYLVSCPHKENCEPKKMGPIRSYLTFVLRPVQRPAQLLDYGDMM 120

Qy        121 LNRGSPSGIWGDSPEDIRKDLPFLGKDWGLEEMSEYADDYRELEKDLLQPSGKQEPRGSA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LNRGSPSGIWGDSPEDIRKDLPFLGKDWGLEEMSEYADDYRELEKDLLQPSGKQEPRGSA 180

Qy        181 EYTDWGLLPGSEGAFNSSVGDSPAVPAETQQDPELHYLNESASTPAPKLPERSVLLPLPT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 EYTDWGLLPGSEGAFNSSVGDSPAVPAETQQDPELHYLNESASTPAPKLPERSVLLPLPT 240

Qy        241 TPSSGEVLEKEKASQLQEQSSNSSGKEVLMPSHSLPPASLELSSVTVEKSPVLTVTPGST 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 TPSSGEVLEKEKASQLQEQSSNSSGKEVLMPSHSLPPASLELSSVTVEKSPVLTVTPGST 300

Qy        301 EHSIPTPPTSAAPSESTPSELPISPTTAPRTVKELTVSAGDNLIITLPDNEVELKAFVAP 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
```

```
Db        301 EHSIPTPPTSAAPSESTPSELPISPTTAPRTVKELTVSAGDNLIITLPDNEVELKAFVAP 360

Qy        361 APPVETTYNYEWNLISHPTDYQGEIKQGHKQTLNLSQLSVGLYVFKVTVSSENAFGEGFV 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 APPVETTYNYEWNLISHPTDYQGEIKQGHKQTLNLSQLSVGLYVFKVTVSSENAFGEGFV 420

Qy        421 NVTVKPARRVNLPFVAVVSPQLQELTLPLTSALIDGSQSTDDTEIVSYHWEEINGPFIEE 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 NVTVKPARRVNLPFVAVVSPQLQELTLPLTSALIDGSQSTDDTEIVSYHWEEINGPFIEE 480

Qy        481 KTSVDSPVLRLSNLDPGNYSFRLTVTDSDGATNSTTAALIVNNAVDYPPVANAGPNHTIT 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 KTSVDSPVLRLSNLDPGNYSFRLTVTDSDGATNSTTAALIVNNAVDYPPVANAGPNHTIT 540

Qy        541 LPQNSITLNGNQSSDDHQIVLYEWSLGPGSEGKHVVMQGVQTPYLHLSAMQEGDYTFQLK 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 LPQNSITLNGNQSSDDHQIVLYEWSLGPGSEGKHVVMQGVQTPYLHLSAMQEGDYTFQLK 600

Qy        601 VTDSSRQQSTAVVTVIVQPENNRPPVAVAGPDKELIFPVESATLDGSSSSDDHGIVFYHW 660
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        601 VTDSSRQQSTAVVTVIVQPENNRPPVAVAGPDKELIFPVESATLDGSSSSDDHGIVFYHW 660

Qy        661 EHVRGPSAVEMENIDKAIATVTGLQVGTYHFRLTVKDQQGLSSTSTLTVAVKKENNSPPR 720
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        661 EHVRGPSAVEMENIDKAIATVTGLQVGTYHFRLTVKDQQGLSSTSTLTVAVKKENNSPPR 720

Qy        721 ARAGGRHVLVLPNNSITLDGSRSTDDQRIVSYLWIRDGQSPAAGDVIDGSDHSVALQLTN 780
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        721 ARAGGRHVLVLPNNSITLDGSRSTDDQRIVSYLWIRDGQSPAAGDVIDGSDHSVALQLTN 780

Qy        781 LVEGVYTFHLRVTDSQGASDTDTATVEVQPDPRKSGLVELTLQVGVGQLTEQRKDTLVRQ 840
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        781 LVEGVYTFHLRVTDSQGASDTDTATVEVQPDPRKSGLVELTLQVGVGQLTEQRKDTLVRQ 840

Qy        841 LAVLLNVLDSDIKVQKIRAHSDLSTVIVFYVQSRPPFKVLKAAEVARNLHMRLSKEKADF 900
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        841 LAVLLNVLDSDIKVQKIRAHSDLSTVIVFYVQSRPPFKVLKAAEVARNLHMRLSKEKADF 900

Qy        901 LLFKVLRVDTAGCLLKCSGHGHCDPLTKRCICSHLWMENLIQRYIWDGESNCEWSIFYVT 960
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
```

```
Db        901 LLFKVLRVDTAGCLLKCSGHGHCDPLTKRCICSHLWMENLIQRYIWDGESNCEWSIFYVT 960

Qy        961 VLAFTLIVLTGGFTWLCICCCKRQKRTKIRKKTKYTILDNMDEQERMELRPKYGIKHRST 1020
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        961 VLAFTLIVLTGGFTWLCICCCKRQKRTKIRKKTKYTILDNMDEQERMELRPKYGIKHRST 1020

Qy       1021 EHNSSLMVSESEFDSDQDTIFSREKMERGNPKVSMNGSIRNGASFSYCSKDR 1072
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1021 EHNSSLMVSESEFDSDQDTIFSREKMERGNPKVSMNGSIRNGASFSYCSKDR 1072
```

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mintz et al (2007/0083334) in view of Campbell (Monoclonal Antibody Technology, 1984, pp. 1-32).

Claim 58 is drawn in part to a method of generating an immune response in a mammalian subject comprising exposing cells of the subjects immune system to a polypeptide comprising SEQ ID NO:5, whereby an immune response comprising the activation of B cells is evoked.

Mintz et al teach the polypeptides of SEQ ID NO:747289 and SEQ ID NO: 747290 which are identical to the instant SEQ ID NO:5. Mintz et al do not teach a method of generating an immune response in a mammal comprising exposure of the mammals immune cells to a polypeptide comprising SEQ ID NO:5.

Campbell teaches that it is customary for any group working on a macromolecule to both clone the genes encoding said macromolecule and make a monoclonal antibody that binds thereto, sometimes without a clear objective for their application (page 29, lines 7-10 under "Basic Research").

It would have been prima facie obvious to one of skill in the art to raise a monoclonal antibody to SEQ ID NO:747289 and/or SEQ ID NO: 747290 by immunizing an experimental

mammal such as a rabbit, mouse or rat to SEQ ID NO:747289 and/or SEQ ID NO: 747290 in order to evoke a B-cell response thereto, so that said B cells or spleen cells maybe isolated therefrom as part of the procedure to make a monoclonal antibody (page 3, Figure 1.1) because it is customary to do so, as exemplified by Campbell.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 79 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 79 recites, the polynucleotide of claim 63 wherein the polypeptide is encoded as a portion of a viral vector. It is unclear how the characteristic of the polypeptide produced from a viral vector further modifies the scope of claim 63 drawn to a polynucleotide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, 56, 63, 79 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(A)As drawn to the peptide fragments of claims 54 and 56

Claim 54 is drawn to a peptide consisting of 9, 10 or 15 contiguous amino acids of SEQ ID NO:3, 5 or 7, wherein the peptide induces a specific antibody response against a polypeptide having the amino acid sequence of SEQ ID NO:3, 5 or 7. Claim 56 is drawn to the peptide of claim 54 consisting of the polypeptide of any of Tables VIII to XLIX.

It is well known in the art that the prediction of protein fragments that will be immunogenic towards the full length protein is unpredictable and that the smaller fragments encompassed by the claims will not predictably be immunogenic, or produce antibodies which will reliably bind to the native antigen..

In particular as drawn to antibodies produced by immunization with peptide fragments, Roit et al (1998, Immunology, 5th ed, pp. 110-111, second paragraph under the heading of "Antibodies recognize the overall conformation of antigens) teach that although it is convenient to synthesize short polypeptide antigens of known primary structure than it is to purify sufficient amounts of native antigen for immunization, antibodies to synthetic peptides often do not bind to the antigen in its native form. This is further exemplified by the teaching of Holmes (Exp. Opin. Invest. Drugs, 2001, Vol. 10, pp. 511-519) who teaches that rabbits were immunized with synthetic peptides which in each case generated high anti-peptide specific immunoreactivities, however, none of the resulting antibodies exhibited binding to the full length antigen. The author concludes that, presumably, expression of these epitopes in the context of the protein was important and affected the antibody binding ability (p. 513, col. 1). Additionally, Tanaka et al. (Proc. Natl. Acad. Sci, 1985, Vol. 82, pp. 3400-3404) tested 35 synthetic peptides of length varying from 7 to 20 amino acid residues for generation of antibodies, and teach that while 31 of 32 peptides of more than 10 residues induced antibodies only 56% of the antipeptide antibodies produced reacted with the native protein, see Abstract, page 3401-3402 and Table 1. Additionally, Tanaka et al. teach that all peptides of fewer than 10 amino acid residues did not induce antibody production and only 1 of 7 peptides of fewer than 13 amino acids produced antibodies that reacted with the native antigen, see Abstract, page 3403, 1st col., and Fig. 1

Further, Paul teaches (page. 249, column 2, lines 9-14) that to determine the immunogenicity of certain regions of a protein, knowledge of the three dimensional structure of the protein is required to determine which polypeptides in a given protein would be accessible on the surface of the protein in order for the putative antigenic determinant to be bound by the antibody. In addition, Paul states that mobility of the putative antigenic determinant within the native protein structure is also a determining factor for the binding of the antigenic determinant to an antibody. Paul points out (page. 250, lines 4-8) that "Measurement of the mobility in the native protein is largely dependent on the availability of a high resolution crystal structure, so its applicability is limited to only a small subset of proteins". The determination of an "epitope" is clearly a non-trivial enterprise, and without further guidance from the specification on known sequences of the BS265 peptide which have been determined to be epitopes in a specific organism, it would require undue experimentation for one of skill in the art to make and use the invention as claimed.

The specification asserts that HLA binding fragments were determined by computer search algorithms (page 93, under Example 13). Burch (WO 03/084467, page 5, lines 18-21, cited in a previous action) teaches that the vast majority of predicted HLA epitopes fail to be immunogenic. One of skill in the art would be subject to undue experimentation in order to test the multitude of epitopes on pages 136-196 for immunogenicity. Applicant has previously argued (January 30, 2007) that it would not require undue experimentation to determine which peptide fragments of SEQ ID NO:3, 5 and 7 were immunogenic. This has been re-considered but not found persuasive. Claims 56 requires that all the peptides listed in the tables VIII to XLIX be immunogenic and the specification has not taught how to use a peptide from said Tables in an alternative use. Therefore one of skill in the art would not know how to use a peptide encompassed by Tables VIII to XLIX that was not immunogenic, or that produced an antibody which did not bind to the native SEQ ID NO:3, 5 or 7.

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as contemplated or claimed with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

(B)As drawn to the polypeptide encoded by the complete complement of SEQ ID NO:3, 5 or 7.

Claim 63 is drawn in part to a complete complement of the polynucleotide encoding SEQ ID NO:3, 5 or 7. Claim 72 requires and expression vector for expressing the polynucleotide of claim 63 which includes the complete complement of SEQ ID NO:3, 5 or 7. Claims 79 and 80 require the polypeptide encoded by the polynucleotide of claim 63. The polypeptide encoded by the complete complement will not produce SEQ ID NO:3, 5 or 7 and the specification has not taught how to use said protein. One of skill in the art would be subject to undue experimentation in order to find a use for such a protein.

Claim 75 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the detection of prostate cancer, does not reasonably provide enablement for the detection of lung, ovarian, breast and pancreatic cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The specification teaches the polynucleotides encoding SEQ ID NOL3, 5 and 7 were isolated from prostate cancer tumor tissue by subtractive hybridization against normal prostate polynucleotides. Thus, SEQ ID NO:3, 5 and 7 are expressed in prostate tumor tissue but not at all, or at a very low level in normal prostate. The specification provides further experiments using a short probe which comprises a polynucleotide sequence common to a partial sequence within the polynucleotide encoding SEQ ID NO:3, 5 and 7 to demonstrate the over expression of said polynucleotide in other types of cancer, such as lung cancer and ovarian cancer in relation to other normal tissues (Example 4, and figures 14B and 16). However, the specification fails to which of any of SEQ ID NO:3, 5 or 7 is translated from the polynucleotide detected by the 254P1D6B probe (SEQ ID NO:1). One of skill in the art would be forced into undue experimentation without reasonable expectation of success in order to use the polypeptides of SEQ ID NO:3, 5 and 7 in the method of diagnosis of non-prostate cancers encompassed by claim 75 if an additional protein isoform which was not any of SEQ ID NO3, 5 or 7 was responsible for the elevated expression of the polynucleotide which hybridized to the 254P1D6B probe (SEQ ID NO:1) in the ovarian cancer and/or lung cancer samples. For example, Conklin et al (Briefings in Bioinformatics, 2000, vol. 1, pp. 93-99) teach that the mining of EST databases

using only a single member of a protein superfamily is prone to false positive hits as some proteins contain common domains (page 95, under the heading "Pruning the False Positives"). In the instant case, SEQ ID NO:1 is 284 bp in length, whereas SEQ ID NO:2, 4 and 6 are 6791, 6791 and 6991 base pairs, respectively. Thus, using SEQ ID NO:1 as a probe is not representative of the polynucleotides encoding SEQ ID NO:3, 5 or 7, and is prone to false positive results with respect to the polynucleotides encoding SEQ ID NO:3, 5 or 7 as taught by Conklin et al. Given the lack of teachings in the specification which address the above issue and the lack of objective evidence that SEQ ID NO:3, 5 and 7 are over expressed in cancers beyond those of prostate cancer, one of skill in the art would be subject to undue experimentation in order to carry out the broadly claimed method.

Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn in light of applicant's arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643